

## REMARKS

Applicant first wishes to thank the Examiner for the allowance of Claims 16-19, 25-29 and 39-42.

The subject application has been carefully considered in view of the Office Action of January 9, 2004. Accordingly, Claims 4-6, 12-15, 22 and 35 are amended to more particularly point out and distinctly claim the invention.

### The Rejection and Arguments

1. Claims 4-6 and 12-14 are rejected under 35 U.S.C. 112 as being indefinite.

Claims 4-6 are amended to delete reference to the blood property change port. Claims 12-14 are amended so they depend from Claim 35 and include a reference to the "dilution indicator port" of Claim 35. The change in dependency and recitation of the indicator port should now provide the claimed terms with a proper antecedent basis.

2. Claims 22 and 24 stand rejected under 35 U.S.C. 102(e) as being anticipated by Quinn, et al. (US 6, 036, 654). For a rejection under 35 U.S.C. 102(e) to stand, each element of a rejected claim must be found in a single reference. This does not appear to be the case here.

Claim 22 as originally presented recites means for performing a "corrective procedure", which is defined at page 22, lines 3-10, as including "removal of a thrombus, angioplasty, atherectomy or dislodgement of a thrombus". It is not seen where Quinn, et al. discloses a comparable means. Quinn, et al. appears to disclose a monitoring apparatus that is capable also of performing certain "therapeutic operation" such as "to infuse fluids or medication" (Column 6, line 20). Applicant asserts such "therapeutic operation" does not constitute the means for effecting a "corrective procedure" as claimed.

To clarify what is meant by a means for effecting a "corrective procedure", Claim 22 is amended to recite a "surgical revision means". Page 3, lines 24-26, of the specification define surgical revision as "including "angioplasty", which is

incorporated with the definition of “corrective procedure “ on page 22. There is no question that no “surgical revision means” is disclosed by Quinn, et al..

Claim 22 further is amended to locate the surgical revision means “downstream of the temperature gradient generator” and to locate the sensor “downstream of the surgical revision means”. Accordingly, even assuming that the Quinn, et al. balloon 32 is a means for effecting a corrective procedure (which it is not), the disposition of this component is at an end of the catheter and not intermediate the temperature gradient generator and sensor as now claimed.

Accordingly, for the reasons noted, the rejection of claim 22 (and dependent claim 24) is traversed.

3. Claims 15, 32, 33, 35, 37 and 38 stand rejected under 35 U.S.C. 102 (b) as being anticipated by Degironimo, et al. (US 4, 502, 488).

Degironimo, et al. discloses a device for performing a variety of diagnostic procedures related to the determination of cardiac output. This includes a thermal dilution measurement wherein a bolus of cold saline is injected and the cardiac output calculated based on the resulting change in blood temperature (Column 4, lines 11-24).

The reference does not disclose any means for performing “a vascular corrective procedure” in the as-filed Claim 15, let alone a “surgical revision means for performing a vascular corrective procedure” as set out in the amended version of Claim 15. The Examiner admits that the reference discloses a balloon for stabilizing the catheter in the heart and not for performing any corrective vascular procedure, but attributes no significance to this because the claim language “constitutes an intended use of the balloon”. This position ignores the structure that is inherent in a means (or surgical revision means) required to perform the “corrective procedure” as defined in the specification (see page 22, lines 3-5). The specification further at page 9, line 13, to page 10, line 23, describes the structural differences between a locator balloon (as used in the reference) and an angioplasty balloon for performing a vascular corrective procedure.

These differences and the structural features of the claimed means as recited in Applicant's specification are inherent in the means plus function recitation in Claim 15 and should not be ignored. These inherent differences do serve to distinguish from the structure disclosed by the reference (which the Examiner even admits does not disclose a means for performing a vascular corrective procedure). The distinction is even more pronounced by the amendment to Claim 15, which now calls for a "surgical revision means for performing a vascular corrective procedure". Certainly, no surgical revision means is disclosed by the reference, so the rejection based on 35 U.S.C. 102(b) is traversed.

Claim 35 similarly is amended to recite that the catheter has a "surgical revision means". No such means is disclosed by the reference, nor does any component of the reference provide for "increasing the effective size of a portion of the vascular passage", so the rejection based on 35 U.S.C. 102(b) is traversed.

Dependent Claims 32, 33, 37 and 38 include all of the limitations of their respective independent claims, so the rejection of these claims under Section 102(b) also is traversed.

4. Claims 2, 3, 9-14, 30, 31, 34 and 36 stand rejected under 35 U.S.C. 102(e) as being anticipated by Quinn, et al. or, in the alternative, under 35 U.S.C. 103(a) as being obvious in view of Quinn, et al.

Claims 9 and 34 are resubmitted unamended for the Examiner's further consideration. In Applicant's view, Quinn, et al. fails to disclose any element that can be equated to the "stenosis reducing member" set out in these claims, let alone be equated to such a member that is "selectively actuatable to reduce stenosis in a vessel". Quinn, et al. discloses a "balloon 32 at the distal tip for flotation". This is a flotation balloon for locating the catheter and is by no means the equivalent of the claimed "stenosis reducing member". Nor does it render obvious the use of a "stenosis reducing member" given the differences in both structure and function. There simply is no suggestion in the reference itself of

providing the disclosed catheter with a stenosis reducing member, and the suggestion to do so appears to be based on hindsight having its genesis in Applicant's disclosure.

As Quinn, et al. lacks the claimed structure (or its equivalent) and offers no suggestion for the inclusion of such structure, Applicant submits that the rejection of Claims 9 and 34 under either 35 U.S.C. 102(e) or 35 U.S.C. 103(a) is traversed.

Accordingly, in view of the above amendments and comments, Applicant considers that independent Claims 9, 15, 22, 34 and 35 are in condition for allowance, which action is respectfully requested. As dependent Claims 2-6, 10-14, 24, 30-33 and 36-38 include all the limitations of the claims from which they depend, these claims also should be in condition for allowance.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Roger Aceto", written over a horizontal line.

Roger Aceto, Registration No. 24, 554  
HARTER, SECREST & EMERY LLP  
1600 Bausch & Lomb Place  
Rochester, New York 14604  
Telephone: 585-231-1118  
Fax: 585-232-2152

Dated: March 24, 2004